implanted ports and therefore had a Vascath placed on the morning of pheresis. Twelve patients completed pheresis and reached target CD34 collection through double lumen CVL. One patient was unable to complete pheresis via his CVL and had a successful pheresis the following day after Vascath placement. Median inlet flow rates were significantly lower in patients undergoing pheresis with a double lumen CVL when compared to patients undergoing pheresis via Vascath and there was a significantly higher rate of pressure error readings in patients with CVLs. Time from admission to start of pheresis was significantly less in patients who underwent pheresis with a CVL. There was no significant difference in time on machine, CD34/kg collected, or number of days of pheresis.

Conclusion: Hematopoietic stem cell pheresis utilizing double lumen CVL is feasible with the potential benefits of shorter hospitalization and avoidance of second line placement.

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Results of a Phase II Study of Propylene Glycol (PG)-Free, Captisol-Enabled Melphalan Conditioning for Autologous Hematopoietic Stem Cell Transplantation (AHCT) in Patients with Multiple Myeloma (MM)

Parameswaran N. Hari [1], *Omar Ajitawi* [2], *Carlos Arce-Lara* [3], *Rajneesh Nath* [4], *Natalie Callander* [5], *Gajanan Bhat* [6], *Lee F. Allen* [6], *Keith Stockerl-Goldstein* [7]. [1] *CIBMTR/Medical College of Wisconsin, Milwaukee, WI;* [2] *Department of Hematology/Oncology, KU Medical Center, Kansas City, KS;* [3] *Division Hematology-Oncology, Medical College of Wisconsin, Milwaukee, WI;* [4] *Department of Medicine; Division of Hematology/Oncology, University of Massachusetts, Worcester, MA;* [5] *Bone Marrow Transplant Program, University of Wisconsin Hospital and Clinics, Madison, WI;* [6] *Spectrum Pharmaceuticals, Irvine, CA;* [7] *Bone Marrow Transplantation & Leukemia Section, Division of Oncology, Washington University School of Medicine, St. Louis, MO*

Melphalan 200 mg/m^2 IV is the most common conditioning regimen for AHCT in MM. Conventional melphalan formulations (eg, Alkeran) have marginal solubility, limited chemical stability and require PG as a co-solvent, which is associated with renal dysfunction and arrhythmias. Captisol-enabled Melphalan HCL (CE-Melphalan) is a PG-free formulation of melphalan that incorporates Captisol, a modified cyclodextrin that improves its solubility, stability and bioavailability. In a previous Phase 2 study, CE-Melphalan was shown to be bioequivalent to Alkeran.

Table 1
Patient Characteristics

	Total (N=61)
Median Age (range) in yrs	62 (32-73)
Age ≥ 65 yrs	30%
Male Gender	57%
Race	
White	80%
Black/African American	18%
Other	2%
ECOG Status	
0	59%
1	38%
2	3%
Disease Status Pre-treatment	
sCR	0%
CR	5%
VGPR	44%
PR	32%
Disease Status at Day 100 post-AHCT	
sCR	13%
CR	8%
VGPR	61%
PR	18%

Table 2
Grade 3/4 Non-hematologic Toxicities

Preferred Term	All Grades % (N=61)	Grade 3/4 % (N=61)
Diarrhea	93	3
Nausea	90	2
Fatigue	77	2
Hypokalemia	74	28
Vomiting	64	0
Hypophosphatemia	49	48
Decreased Appetite	49	0
Pyrexia	48	3
Constipation	48	0
Febrile Neutropenia	41	28
Mucosal Inflammation	38	10
Dizziness	38	0
Stomatitis	28	5
Abdominal Pain	28	0
Dysgeusia	28	0
Dyspepsia	26	0

Methods: This Phase II, open-label study enrolled 61 pts with MM who received 200 mg/m^2 of CE-Melphalan (100 mg/m^2/day x 2) followed by AHCT. Most subjects were male (57%) with a median age of 62.0 years (range 32-73), including 56 (92%) subjects who received upfront AHCT and 5 (8%) after relapse (Table 1). Median lines of prior therapy was 3 (range 2-16). High risk cytogenetics in 6 (10%) pts. Disease status at pre-treatment included CR in 3 subjects, VGPR in 27 and PR in 20 subjects.

Results: All subjects achieved myeloablation followed by successful engraftment. Median time to neutrophil engraftment was 12 days post-AHCT (range: 10-12); time to platelet engraftment was 13 days (range 10-28). There was no mortality by Day 100, and as expected the most common Grade 3 and 4 toxicities were hematologic. Non-hematologic toxicities are summarized in **Table 2**. Severe mucositis was reported in few patients (Grade 3/4; 10%). At Day 100 post-AHCT, all patients (100%) had a response with 82% of subjects achieving a >= VGPR response including sCR in 13%, CR in 8% and VGPR in 61%.

Conclusions: CE-Melphalan led to successful myeloablation and subsequent engraftment in MM patients with no mortality or unexpected transplant-related toxicity over conventional melphalan. The incidence of Grade 3-4 mucositis was low. Overall, 100% of subjects responded to high dose CE-Melphalan, and in the subgroup of high risk patients (n=6, 10%), an encouraging 67% VGPR or better responses were achieved.

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Combination Antiretroviral Therapy during Autologous Stem Cell Transplant for HIV Infected Patients with Haematological Malignancies

Karim Ibrahim [1], *Samuel Milliken* [2]. [1] *Pharmacy, St. Vincent's Health Network, Darlinghurst NSW, Australia;* [2] *Department of Hematology, St. Vincent's Hospital, Darlinghurst NSW, Australia*

In the post combination antiretroviral therapy (cART) era, HIV infected patients are better able to tolerate chemotherapy for HIV-associated lymphoma and results of the treatment are similar now to non-HIV infected patients. Consequently the use of hematopoietic stem cell transplant (HSCT) has been investigated in the post cART era. One of the main challenges that faces clinicians though is the potential for cART and chemotherapy drug-drug interactions.